REMARKS

Claims 1-23 are pending in the application. Claims 1, 12, 14 and 19 have been amended. Support for all amendments can be found in the specification as originally filed.

Claim Objections

Claim 14 stands objected to as containing informalities In the Claim language. Applicants have amended the claims to attend to the Examiner's objections. Reconsideration of the Examiner's objections is respectfully requested.

Rejections Under 35 USC 112, second paragraph

Claims 1 and 14 stand rejected under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Accordingly, Claim 1 has been amended for further clarification to indicate that the phrase "a body comprising a rearward end and a forward end, wherein the rearward end is adapted to attach to the injector." Reconsideration of the Examiner's rejection is respectfully requested.

REJECTIONS UNDER 35 USC 102(b)

Claims 19 and 20 stand rejected under 35 USC 102(b) as being anticipated by et al. (hereinafter "Neer").

It is well settled that in order for a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in prior art. The disclosure requirement under 35 USC 102 presupposes knowledge of one skilled in art of claimed invention, but such presumed knowledge does not grant license to read into prior art reference teachings that are not there. See *Motorola Inc. v. Interdigital Technology Corp.*

43 USPQ2d 1481 (1997 CAFC). It is also well-settled that a 35 USC 102 rejection must rest upon the literal teachings of the reference and that the teachings must disclose every element of the claimed invention in as complete detail as is contained in the claim (See. *Jamesbury Corp v. Litton Industrial Products, Inc.* 225 USPQ, 253, 256 (CAFC 1985); *Kalman v. Kimberly-Clark Corp* 218 USPQ 781, 789 (Fed. Cir. 1983)).

The Office Action alleges that the syringe comprises a body 30 ...and a flexible ring 46 operable to releasably attach the syringe to the injector; wherein the rotation of the syringe about its axis when attached to the injector causes deformation of the flexible ring to enable detachment of the syringe from the injector 45 (see Office Action para 11). However, Neer discloses a syringe 32 that is separate from the pressure jacket assembly 30. "The jacket 31 is made of a stronger transparent material that will withstand the operating pressures. When the syringe 32 is contained in the jacket 31, it is surrounded by the jacket 31 and supported by the jacket 31 against expansion caused by the fluid pressure within as the syringe 32 expands against the jacket wall. The pressure jacket 31 has a generally cylindrical inner bore 33 extending therethrough from a proximate end 34 adjacent the door 25 to a remote end 35 of the pressure jacket 31 toward the front of the unit 20. The bore 33 is dimensioned so as to receive through the remote end 35 the disposable syringe 32 and to support the syringe against expansion from fluid pressure within such fluid pressure may range to more than a thousand psi. " (Col. 7, lines 33-43). Neer also discloses that the syringe 32 includes a syringe case 50 formed of a single piece of molded plastic. Additionally, Neer discloses that:

> The syringe 32 includes structure that is configured to lock the syringe 32 to the front end of the jacket 31 by cooperating with mating structure on the jacket 31. The jacket 31 has, spaced around the circumference thereof near the remote or front end 35 of the jacket 31, four equally spaced outwardly projecting thread sections 85. ... When so inserted, the syringe assembly 32 with the cap 51 may be twisted clockwise 45.degree. to tighten and thereby secure the cap 51 to the jacket 31 by engagement between the threads 85 and 86 as shown in FIG. 5, to thereby lock the syringe in the bore 33. " (col. 8, lines 63 – Col. 9 line).

Thus, the syringe body 50 is not part of the pressure jacket. Therefore, Neer does not disclose Applicants' invention of Claim 1, including "at least one attachment member associated with the body, the at least one attachment member cooperating with the flexible ring of the syringe retaining mechanism to releasably attach the syringe to the injector."

Further, the Office Action alleges that Neer discloses at least one attachment member comprising a flexible ring 46 operable to releasably attach the syringe to the injector 46, and that the Examiner notes that the O-ring 46 is fully capable of performing the function. However, the O-ring does not operate and deform to release that syringe from attachment with the injector upon rotation of the syringe about an axis relative to the injector. Rather, the O-ring merely surrounds the flange 37 of the jacket 31 in the recess of the door 25. (Col.7, lines 59-61). The O-ring is disposed between the door 25 of the housing 21 (see Fig.'s 2-4) and does not releasably engage any part of the syringe. Accordingly, Neer does not disclose "at least one attachment member associated with the body, the at least one attachment member comprising a flexible ring operable to releasably attach the syringe to the injector" of Applicants' invention of Claim 19.

Claim 20 depends from Claim 19, which as discussed herein is believed to be allowable. Thus, Claim 19 is also believed to be allowable. Accordingly, reconsideration of Claim 19 is respectfully requested.

2. Claim 19 stands rejected under 35 USC 102(b) as being anticipated by Bendek et al. (hereinafter "Bendek"). This rejection should be withdrawn in view of the remarks made herein.

The Office Action alleges that Bendek discloses an injector having at least one attachment member 18 a,c associated with the body and the at least one attachment member comprising a flexible ring 18 a,c. However, Bendek discloses an injection device 10 including a cartridge retainer 18. "The proximal end 18b of cartridge retainer 18 includes a pair of angular projections 18c that are spaced to receive angular projections 30c when cartridge retainer 18 is

mounted on housing 20, which is described further below. " (Col. 4, lines 21-24). "The proximal end of cartridge retainer 18 includes the pair of bayonet lugs 18a on angular projections 18c that engage with the pair of slots 16a at the distal end of center body 16." (Col. 6, lines 5-8) "After a cartridge 46 has been loaded into cartridge retainer 18, cartridge retainer 18 is mated with center housing 16 such that lugs 18a enter slot 16a." (Col. 4, lines 54-57). Thus, Bendek discloses inflexible and rigid lugs 18a on angular projections 18 c. Once the lugs 18a enter slot 16a then as shown in Fig. 8 the retainer 18 is rotated such that the lugs 18a drive tabs 30c. (col. 4, lines 57-59); the lugs are not flexible. Further, the lugs 18a (and angular projections 18c) are disposed on the cartridge retainer 18 which is not a syringe body. Thus, Bendek does not disclose "a plunger sealing disposed movably disposed within the body; and at least one attachment member associated with the body, the at least one attachment member comprising a flexible ring operable to releasably attach the syringe to the injector" of Applicants' invention of Claim 19. Reconsideration is requested.

REJECTIONS UNDER 35USC 102(e)

1. Claim 13 stands rejected under 35 USC 102(e) as being anticipated by Fago et al (herein "Fago"). This rejection should be withdrawn in view of the remarks made herein.

The Office Action alleges that Fago discloses an injector having a syringe retaining mechanism operable to release the syringe upon axial rearward motion of the syringe relative to the syringe retaining mechanism regardless of the orientation and the syringe retaining mechanism consisting essentially of a flexible ring. However, Fago discloses that:

> Referring now to FIGS. 8 and 9, the motion of sealing arms 90a and 90b from their open position of FIG. 8 to their closed position of FIG. 9 can be illustrated. Specifically, when a syringe is inserted into face plate 86 in the orientation shown in FIG. 8, and then turned clockwise to the orientation shown in FIG. 9, this rotational motion causes sealing arms 90a and 90b to similarly rotate clockwise from the open positions shown in FIG. 8 into the closed positions shown in FIG. 9. As can be seen in FIG. 9, in their

closed positions the interior edges 92a and 92b of sealing arms 90a and 90b engage the outer cylindrical wall 80 of the syringe and form a seal therewith, thus inhibiting leakage of spilled fluid along the wall of the syringe. (The interior edges 92a and 92b of sealing arms 90a and 90b may carry rubber or other flexible seals such as are shown at edges 92a and 92b illustrated in FIG. 10.) At the same time sealing arms 90a and 90b lend mechanical stability to the syringe when it is mounted on the injector face plate 86.

Now referring to FIGS. 8, 9 and 10, in the illustrated embodiment, rotation of arms 90a and 90b is generated through mechanical mechanisms including a lever arm 94, which drives a pinion gear 96, which meshes with a main gear 98 rotationally coupled to the sealing arm 90. Clockwise rotation of the syringe from the position shown in FIG. 8 to the position shown in FIG. 9, causes locking flange 82 of the syringe to engage and rotate lever arm 94 counterclockwise. Counterclockwise motion of lever arm 94 causes counterclockwise motion of pinion gear 96. Pinion gear 96, meshing with main gear 98, causes main gear 98 to rotate clockwise, driving the connected sealing arm to rotate clockwise to its closed position.

As shown in FIG. 10, main gear 98 is rotationally locked to a shaft 100, which passes through face plate 86 and into sealing arm. Thus, rotation of main gear 98 causes rotation of shaft 100 and corresponding rotation of sealing arm 90b. A torsion spring 102 coupled between main gear 98 and face plate 86 produces a return force tending to rotate main gear 98, shaft 100 and sealing arm 90 counterclockwise to an open position whenever the syringe is rotated counterclockwise toward its disengaged position.

Thus, Fago discloses two rigid arms 90a,b that are rotated from an open position to a closed position, however, the arms are not flexible, otherwise they would not be able to lend mechanical stability to the syringe when it is mounted and they are not a ring shaped. Further, the interior edges 92a and 92 b of the sealing arms 90a and 90b may carry rubber seals, however, these does not releasbly seat the syringe with axial rearward motion. The interior edges would be moved with the arms 90a,b when the arms are rotated about the syringe. Therefore Fago does not discloses Applicants' invention of Claim 13 including "a syringe retaining mechanism associated with the housing and being operable to releasably seat the syringe upon axial rearward motion of the syringe relative to the syringe retaining mechanism regardless of the orientation of syringe about

the axis of the syringe, the syringe retaining mechanism consisting essentially of a flexible ring maintained at a fixed axial position within the syringe retaining mechanism." Reconsideration is requested.

2. Claims 13 and 19 stand rejected under 35 USC 102(e) as being anticipated by Trocki et al (herein "Trocki"). This rejection should be withdrawn in view of the remarks made herein.

Trocki is an inventor in the present Application, and thus the invention of the present application is not by another. Therefore, oath/declaration is forthcoming and Applicants ask that reconsideration be given.

Double Patenting

1. Claim 1-17 and 19-21 stand rejected as being unpatentable over Claim 16-39 and 53 of U.S. Pat. No. 6652489 (herein "Trocki) under nonstatutory obviousness-type double patenting.

The Claims of Trocki are directed to a syringe that is patentably distinct. Trocki discloses at least one release member associated with the body, the at least one release member operable to cause deformation of the flexible ring to enable release of the syringe from attachment with the injector upon rotation of the syringe about its axis relative to the injector in Fig. 56. In particular, "as shown in FIGS. 55-57, ridge 4044 includes two parts, a sloping section 4046 and a shoulder section 4048 that is essentially perpendicular to the exterior surface of cylindrical body 4030. At least one, and preferably two or more, extending tabs or projections 4050 are provided at rear end 4022 of syringe 4012. Tabs 4050 engage grooves 4052 provided in ring 4028. " (col. 33, line 64 to col. 34, line 3). This is very structurally different from Applicants' invention having a least one release member being axially forward of the at least one attachment member. Thus, reconsideration is requested.

2. Claims 1-17 and 19-21 stand rejected because they conflict with claims 13-21 of Application number 10/668673.

The claims of the present invention are novel over claims of Application No. 10668673. The retention of Claims 1-17 and 19-21 during the pendency of this Application is needed because the scope of Claims 1-17 and 19-21 includes inventions that are not anticipated by Trocki. Reconsideration is requested.

In view of the above amendments and remarks, applicants respectfully requests that the Examiner, indicate the allowability of the claims and arrange for an official Notice of Allowance to be issued in due course.

Respectfully submitted,

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By /
Jill Denesvich
Reg. No. 52,810

MEDRAD, INC.
One Medrad Drive
Indianola, PA 15051
(412) 767-2400 (phone)
(412) 767-8899 (fax)
Attorney for Applicants

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